

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

(iii) collecting sufficient fluid of said sample so that said sample passes over said indicator means in or associated with said channel portion; and

312
(iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.

REMARKS

Reconsideration of all grounds of rejection and allowance of all appending claims are respectfully requested in light of the above amendments and the following remarks.

Claim 26 has been cancelled without prejudice or disclaimer. Claims 1, 6, 8, 11, 17, 19-25, 27, 29, and 31 have been amended to improve clarity.

1. Applicant has amended the specification as requested by the examiner to reflect that priority is claimed from PCT and UK Applications.

2. Applicant has attached an Abstract of the Disclosure in accordance with U.S. practice

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

3. Claims 1, 8 and 19-25 stand rejected under 35 U.S.C. §112, second paragraph, for the reasons indicated in the Office Action. Claim 1 has been amended to remove the recitation that the substrates size is predetermined; claim 8 has been amended to remove the phrase "or the like"; and claims 19-25 have been amended to recite a test kit comprising a pouch in combination with the test device.

Accordingly, it is respectfully submitted that all grounds of rejection under 35 U.S.C. §112 have been overcome. Reconsideration and withdrawal of these grounds of rejection are respectfully requested.

4. Claims 19-25 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Haswell (U.S. 5,520,041). It is respectfully submitted that this ground of rejection is traversed for the reasons indicated below.

According to the Office Action, Haswell discloses a pouch for a sample card having a predetermined size and shape, and the pouch is equipped with a desiccant packet. The pouch is also lined with a fluid impervious material.

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

However, it is respectfully submitted that Applicant has amended claims 19-25 to recite a test kit comprising a combination of the test device according to claim 1 and the pouch.

Accordingly, it is respectfully submitted that claims 19-25 are not anticipated by Haswell, nor would they have been obvious to a person of ordinary skill in the art in view of this reference. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

5. Claims 1-18 and 26-31 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ostrup (U.S. 5,460,057) in view of Sangha (U.S. 5,334,502). It is respectfully submitted that this ground of rejection is traversed for the reasons indicated herein below.

According to the Office Action, Ostrup discloses an apparatus for handling biological samples including a sample collection unit/card having a substrate with several apertures. An absorbent filter paper is disposed over each aperture and the card is provided with a mark to indicate the location of an acceptable

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

The Office Action admits that Ostrup does not teach a guide means having a sample deposition portion connected to a channel portion.

However, Sangha discloses a device for collecting biological samples comprising an absorbent layer onto which a sample is deposited. As the user deposits the sample onto the center portion of the absorbent layer, a one-way barrier leads the sample to the indicator where a colored signal will denote the presence of a sufficient amount of sample. Thus the Office Action alleges that it would have been obvious to a person of ordinary skill in the art to use a guide means as allegedly disclosed by Sangha in the sample collection card of Ostrup for the purpose of alerting the user of the presence of a sufficient amount of sample on the card.

However, Applicant respectfully submits that the presently claimed invention recites a testing device having a substrate including at least one indentation or aperture suited for access by an automatic testing apparatus after the sample has been collected. Supportive material for collecting the fluid sample is mounted on the substrate and positioned relative to the indentation or aperture, and serves as a guide for where the sample should be placed. Thus, the arrangement serves as a guide for a user as to

exactly where the sample should be placed on the supportive material.

In a particular embodiment, the substrate is provided with an aperture to which the supportive material can be accessed, the sample is collected on the supportive material accessed through the aperture, and can subsequently be punched out in a conventional manner for analysis by an automated testing apparatus, with the knowledge that the sample is securely contained on the specific portion of the supportive material and not elsewhere.

One advantage of the presently claimed invention is that the arrangement of the indentation or apertures does not require an operator to judge by eye, or require a machine to make a determination after viewing by camera (such as Ostrup) as to where on the absorbent paper is the best area for punching. In the prior art, whether the determination is made by an operator's judgement, or by a testing device, the consistency of the sampling is reduced.

However, in the present invention, as the substrate is provided with an aperture to which the supportive material can be accessed, the need for manual intervention by an operator to judge the best portion of the paper that should be punched, (or the

requirement that such a determination be made by an automatic system), is eliminated.

In addition, another advantage of the presently claimed invention that is not disclosed, suggested or motivated to an artisan by the combination of Ostrup and Sangha is that the supportive material comprises a guide means comprising a sample deposition portion and attached to a channel portion. The channel portion includes an indicator means arranged at a predetermined distance away from the sample deposition portion. The arrangement of the indicator means in the channel portion at a distance away from the sample deposition portion provides the advantage (envisioned in an embodiment) that the presently claimed invention can be used by people in the privacy of their homes without the need for professional supervision because the indicator means will only indicate a sufficient amount of sample has been collected when the whole sample area is adequately wetted. In other words, in the prior art such as Sangha, a user may deposit an inadequate sample, but may do so right next to or at the location of the indicator means. Thus the indicator in Sangha will change color indicating that the sample is sufficient, but in fact the sample is insufficient for testing purposes.

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

Another reason for a possible erroneous indication of adequacy in Sangha is because the part of the sample which mixes with the indicator means to change color is in effect contaminated by the indicator, and there may not be sufficient sample on the sample deposition portion that does not include the indicator material to insure proper analysis by a testing device. Thus, in the prior art such as Sangha, an inadequate sample can still cause the indicator to falsely indicate that there has been an adequate sample collected because the person using the testing device deposited an inadequate sized sample but happened to do so in the area of the indicator means.

In contrast, in the presently claimed invention, the sample deposition area and the indicator means are away from each other. Thus, the possibility that the user has not provided a sufficient sample is eliminated because there must be enough sample to travel along the channel portion and contact the indicator means. This structure prevents a false indication of adequacy because the user happened to deposit a smaller than required sample on or next to the indicator itself. Thus the presently claimed invention insures that the entire aperture area is provided with an adequate sample.

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

DOCKET NO. 2386-1-001

The presently claimed invention overcomes, *inter alia*, 1) the prior art problems of accurately identifying that a sufficient quantity of sample has been collected; and 2) eliminates the need to identify where the best concentration of sample can be found on the absorbent paper.

The presently claimed invention also eliminates the requirement to judge or measure where to punch out a sample for analysis after inspection of the deposition of the sample, since the whole sample area is adequately wetted.

Applicant also respectfully submits that Ostrup, in contrast, discloses an automated inspection system including a camera to find the optimum point for punching without the mark 34 based on visual examination (see column 7, lines 47-51), or in an alternative embodiment, requires a mark 34 on the covering of the filter paper to identify the location of an acceptable sample. Thus, Ostrup requires the need to identify an optimum punching site. Ostrup discloses the problem of sample insufficiency, but whether the mark 34 is made by a user following visual observation or the use of a camera to find an optimum point 35, either results in a complex system that is still prone to error and insufficient sampling.

Applicant respectfully submits that in Ostrup, the substrate is merely a course locator for the location of a blood sample, and is used to insure that a large number of samples can be collected and kept apart by providing a large number of sample collection areas. Once a sample is collected, there is still a need for identifying the precise location within the area defined by the aperture in the substrate.

Finally, Applicant notes that Sangha discloses that a sample is provided on the center portion of an absorbent layer and wicks out to a circumferentially located color indication portion. However, Applicant respectfully submits that Sangha does not disclose or suggest a guide means to guide a sample from a sample deposition portion to an indicator portion which is arranged at a predetermined distance away from the sample deposition portion. If the entire sample collection portion in Sangha is collected for analysis, it is respectfully submitted that portions of the sample will be contaminated because of the arrangement of the indicator means within the sample collection area.

Accordingly, it is respectfully submitted that none of the present claims would have been obvious to a person of ordinary skill in the art over the combination of Ostrup and Sangha. The

AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

APPLICATION NO. 09/230,130

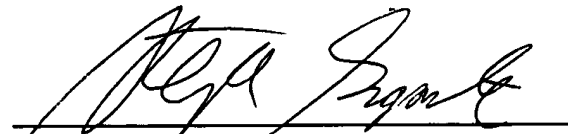
DOCKET NO. 2386-1-001

combination of Ostrup and Sangha fails to disclose, suggest or motivate to a person of ordinary skill in the art the structure of Applicant's claimed test device. It is respectfully submitted that Applicant's test device is unobvious to a person of ordinary skill in the art over the combination of Ostrup and Sangha, or any of the prior art for that matter, and offers advantages over all of the prior art, including the combination of Ostrup and Sangha.

For all the foregoing reasons, it is respectfully submitted that all grounds of rejection in the Office Action have been overcome. A Notice of Allowance is respectfully requested.

If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to kindly telephone the undersigned at the telephone number listed below.

Respectfully submitted,



Stephen Gigante
Attorney for Applicant
Registration No. 42, 576

Date: August 22, 2001

SG/lc

Enclosure

Attorney Docket No. 2386-1-001

KLAUBER & JACKSON
411 Hackensack Ave
Hackensack, New Jersey 07601
(201) 487-5800